

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

NEUROSURGICAL CARE, LLC	:	
	:	
Plaintiff,	:	
	:	
v.	:	Case No. 2:19-cv-05751-JMY
	:	
BIEGLER GMBH; SOLACE	:	
ADVANCEMENT, LLC; JAMES W.	:	
CARPENTER; DOC SOLUTIONS LLC;	:	
MARK KAISER; LIZ O'NEILL; ABC	:	
CORPS 1-50; and JOHN DOES 1-50,	:	
	:	
Defendants.		

FIRST AMENDED COMPLAINT

Plaintiff, Neurosurgical Care, LLC, a Pennsylvania Limited Liability Company (“Neurosurgical Care” or “Plaintiff”), by and through its undersigned attorneys, brings this Complaint against Defendants Biegler GmbH (“Biegler”), Solace Advancement LLC (“Solace Advancement”), James W. Carpenter (“Carpenter”), Doc Solutions LLC (“Doc Solutions”), Mark Kaiser (“Kaiser”), Liz O’Neill (“O’Neill”), ABC Corps. 1-50, and John Does 1-50 (collectively referred to as “Defendants”). In support of its Complaint, Plaintiff Neurosurgical Care hereby alleges as follows.

BACKGROUND

1. The Stivax System (“Stivax”) is a single use, battery-powered, electrical nerve stimulator which is used for the stimulation of the cranial nerves innervating the ear to treat back, joint and arthritic pain.

2. Defendants orchestrated a fraudulent marketing scheme to sell Stivax in the United States as Medicare reimbursable, knowing at all times it was not. As a result of this fraudulent scheme, purchasers of Stivax across the nation, like Plaintiff, purchased Stivax from

Defendants, administered Stivax to patients, and, relying on Defendants' misrepresentations that Stivax was Medicare reimbursable, billed Medicare.

3. Stivax is manufactured by Biegler, who also manufactured the P-STIM System ("P-STIM"). Although Biegler was likely advised by CMS in November 2014 that P-STIM was not eligible for Medicare reimbursement, CMS publicly declared P-STIM was not Medicare reimbursable on October 22, 2015. This fact was known to the P-STIM distribution network in the United States, which included Defendant James W. Carpenter through an entity he owned known as Eagle Advancement Institute.

4. By April 24, 2016, Biegler sought approval from the U.S. Food & Drug Administration ("FDA") to market a repackaged P-STIM product, Stivax, and did so based on the representation that Stivax was the substantial equivalent of P-STIM. FDA approved this request on May 26, 2016, and concluded Stivax was the substantial equivalent to its predicate device, P-STIM.

5. Once approved in May 2016, only a few months after P-STIM was announced as ineligible for Medicare reimbursement, Stivax was being imported to the United States pursuant to Biegler's agreement with Solace Advancement founded by Carpenter; and distributed and sold across the United States pursuant to distribution agreements between Solace Advancement and distributors like Doc Solutions, ABC Corps and John Does. This is the Stivax Enterprise, and its purpose was to sell Stivax throughout the United States, and it did so pursuant to the common scheme or plan which included knowingly misrepresenting Stivax as Medicare reimbursable.

6. Based on the misrepresentation by the Stivax Enterprise that Stivax was Medicare reimbursable, Plaintiff and the Class purchased Stivax and submitted claims to Medicare for

reimbursement. The impact of this conduct, improper Sivax claims being submitted to Medicare for reimbursement based on the misrepresentations of the Stivax Enterprise, is ongoing.

PARTIES

PLAINTIFF NEUROSURGICAL CARE, LLC

7. Plaintiff Neurosurgical Care is a Pennsylvania Limited Liability Company that provides outpatient medical services, located in Royersford, Pennsylvania.

8. Neurosurgical Care was founded by Dr. Sagi Kuznits, a board-certified and practicing neurosurgeon, who performs mainly inpatient neurosurgeries at hospitals in Paoli, Pottstown, and Phoenixville, Pennsylvania, and for some of these hospitals he is the only neurosurgeon.

9. Dr. Kuznits performs spinal surgeries to alleviate pain arising from impinged nerves and weakened spine segments due to degenerative, traumatic, neoplastic, and infectious etiology.

10. At Neurosurgical Care, Dr. Kuznits provides pre-operative and post-operative care to patients, as well as offers alternatives to invasive surgeries to improve the management of severe, chronic pain.

11. While trained as a surgeon, Dr. Kuznits is interested in using all modalities he has found effective to improve the control of severe, chronic pain, including less invasive electronic stimulation procedures that do not have the potential concomitant addictive effects of opioid prescriptions.

12. One technology that Dr. Kuznits has found effective for his patients' pain management is neurostimulation, a method of stimulating the nervous system to assist individuals in reducing their chronic pain.

13. In particular, Dr. Kuznits used and administered Stivax to his patients in order to assist with the treatment of their chronic pain.

14. Stivax was marketed and sold to Dr. Kuznits by Doc Solutions and Mark Kaiser, an authorized Stivax distributor.

15. Doc Solutions and Mark Kaiser specifically advised Neurosurgical Care to bill Medicare and other government health care payors for Stivax using codes that they knew to be improper.

16. Neurosurgical Care used these codes, and, as a result, has been harmed by the fraudulent billing and coding information provided by Doc Solutions and Mark Kaiser.

17. Neurosurgical Care seeks damages from Doc Solutions and Mark Kaiser to compensate for the damages suffered as a result of the knowingly fraudulent information peddled by Doc Solutions and Mark Kaiser.

18. In November 2016, Dr. Kuznits worked with Tena Harwick, Accounting for Eagle Advancement Institute, to secure his P-STIM System training through the portal Pstim.us, and he received his P-STIM System training certificate on or around November 14, 2016. The Pstim.us portal is no longer operational, and Tena Harwick serves the same role for Solace Advancement who is the U.S. Distributor for Stivax.

19. In December 2018, Plaintiff Neurosurgical Care and Dr. Sagi Kuznits received Civil Investigative Demands from the United States Attorney's Office for the Eastern District of Pennsylvania and have been subjected to an investigation relating to their billing of Stivax under Medicare billing code L8679 as directed by the Stivax Enterprise.

DEFENDANT BIEGLER GMBH

20. Defendant Biegler GmbH is an Austrian company with its principal place of business in Mauerbach, Austria.

21. Biegler is the manufacturer of both the P-STIM and Stivax devices, and responsible for the FDA approval to market both P-STIM and Stivax in the United States.

22. Biegler retained the services of Promedic, Inc., and its President Paul Dryden, as their Agent in the United States to obtain approval from the FDA to market both P-STIM and Stivax.

23. Biegler communicated directly with CMS and victims of the Stivax Enterprise's fraudulent scheme via e-mail and letter about P-STIM and/or Stivax.

24. Biegler engaged Carpenter and Solace Advancement as the U.S. Distributor for Stivax.

25. Biegler knowingly misrepresented Stivax as Medicare reimbursable to Plaintiff and other Class members through the Stivax Enterprise.

DEFENDANTS SOLACE ADVANCEMENT LLC and JAMES W. CARPENTER

26. Defendant Solace Advancement LLC is a Michigan Limited Liability Company owned and operated by James W. Carpenter.

27. Solace Advancement operates as the primary U.S. distributor for Stivax pursuant to its contract with Biegler.

28. Solace Advancement distributes Stivax across the United States pursuant to agreements with other distributors it engages, including Doc Solutions, ABC Corps. 1-50 and John Does 1-50.

29. Solace Advancement is a distributor of Stivax, and promoted, marketed, and distributed Stivax to Neurosurgical Care and other Class Members.

30. Solace Advancement and Carpenter knowingly misrepresented Stivax as Medicare reimbursable to Plaintiff and other Class members through the operation of the Stivax Enterprise.

31. Carpenter also owns Eagle Advancement Institute, who is the U.S. distributor for P-STIM.

32. Carpenter is personally liable for the actions of Solace Advancement and the Stivax Enterprise because it was established to perpetrate the fraud of the Stivax Enterprise, and upon information and belief, it is undercapitalized, operates without corporate formalities, and fails to maintain an independent corporate identity.

DEFENDANTS DOC SOLUTIONS LLC, MARK KAISER AND LIZ O'NEILL

33. Defendant Doc Solutions LLC ("Doc Solutions") is a Florida Limited Liability Company, with a principal place of business listed at 6160 State Road 70 E #103, Bradenton, FL 34203, and a mailing address of 1767 Lakewood Ranch Blvd. #326, Bradenton, FL 34211. Doc Solutions is owned by Kaiser and O'Neill.

34. Doc Solutions is a distributor of Stivax, and promoted, marketed, and distributed Stivax to Plaintiff and other Class Members pursuant to its agreement with Solace Advancement.

35. Doc Solutions and Kaiser knowingly misrepresented Stivax as Medicare reimbursable to Plaintiff and other Class members through the operation of the Stivax Enterprise.

36. Kaiser and O'Neill are personally liable for the actions of Doc Solutions and the Stivax Enterprise because it was established to perpetrate the fraud of the Stivax Enterprise, and

upon information and belief, it is undercapitalized, operates without corporate formalities, and fails to maintain an independent corporate identity.

DEFENDANTS ABC CORPS 1-50 and JOHN DOES 1-50

37. Defendants ABC Corps 1-50 and John Does 1-50 are corporate entities and individuals within the Stivax Enterprise that Defendants' co-conspirators yet to be identified, but are known to Biegler, Solace Advancement and/or Carpenter.

JURISDICTION AND VENUE

38. Plaintiff repeats, realleges, and incorporates here by reference each of the foregoing and subsequent allegations of this Complaint as if set forth fully herein.

39. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332, because this is a civil action between citizens of different states and the amount in controversy exceeds \$75,000.

40. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1964(c) as Plaintiff contends that Defendants committed violations of 18 U.S.C. §§1962(c), (d).

41. This Court has personal jurisdiction over the Defendants because they did business in this state and District, and they have sufficient minimum contacts in this state and District through the promotion, marketing, and sale of Stivax in this state and District, such that the exercise of jurisdiction by this Court is permissible under traditional notions of fair play and substantial justice.

42. Venue is proper in this Court under 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims here occurred in the Eastern District of Pennsylvania. Defendants marketed and sold Stivax in this state and District, Defendants received

substantial compensation and profits from the sale of Stivax within this state and District, and engaged in deliberate or, at best, negligent misrepresentations concerning the correct billing, coding, and reimbursement for Stivax within this state and District, and the transactions between the Defendants and Neurosurgical Care LLC occurred in this state and District, and a substantial part of the property that is the subject of this action is situated in the District.

43. Venue is also proper under Section 1391(c) because Defendants are subject to this Court's personal jurisdiction in the District.

FACTUAL BACKGROUND

A. THE P-STIM SYSTEM

44. The P-STIM System is a miniaturized, battery-powered, transcutaneous electrical nerve stimulator that has a pre-programmed frequency, pulse, and duration for the stimulation of auricular acupuncture points. The P-STIM System is intended for use as an electro-acupuncture device to stimulate appropriate auricular acupuncture points.

45. On January 17, 2005, Biegler, through its U.S. distributor at the time, NeuroScience Therapy Corp., submitted a premarket approval application ("PMA") to the FDA pursuant to Section 510(k) (K050123). On March 30, 2006, the FDA determined the P-STIM System was the substantial equivalent to legally marketed predicate devices prior to May 28, 1976, so Biegler was able to market the P-STIM System.

46. Biegler manufactured the P-STIM and distributed it through a licensing arrangement with Dyansys, Inc. until July 2013. In May 2013, Biegler learned the principal of Dyansys, Inc., Srinivasa Nageswar, applied to CMS seeking the creation of a billing code within the Healthcare Common Procedure Coding System ("HCPCS") for the P-STIM System. No HCPCS code existed for the P-STIM System.

47. CMS scheduled the request for a hearing on May 29, 2013 during a HCPCS Public Meeting as Agenda Item #6. Biegler objected to the HCPCS code application submitted by Mr. Nageshwar on May 23, 2013, explaining that Mr. Nageshwar was not the manufacturer of P-STIM and not authorized by Beigler to submit the application. *See* May 23, 2013, Letter from Ingeborg Biegler, Managing Director of Biegler attached as **Exhibit A**.

48. Biegler requested CMS remove the application to create a HCPCS code for the P-STIM System from the May 29, 2013 Agenda, stating it is Biegler's "intention to pursue a HCPCS code at some future time when we are ready to do so" *Id.* The Agenda item was removed and no decision rendered regarding a billing code during the May 23, 2013 HCPCS Public Meeting.

49. After Biegler terminated Dyansys, Biegler entered into a distribution and licensing arrangement with Innovative Health Solutions, Inc. ("IHS") and Eagle Advancement Institute to distribute the P-STIM System in the United States.

50. On March 28, 2014, Biegler engaged ProMedic, Inc. and its President, Paul Dryden, to submit another PMA for the P-STIM System (K140788).

51. While the PMA for the P-STIM System (K140788) was pending, upon information and belief, Biegler orchestrated the submission of Agenda Item #14 to the CMS HCPCS Public Meeting Agenda on May 28, 2014: "Request to establish a new level II HCPCS code to identify an auricular point stimulation (Electro-Acupuncture Stimulator) device, trade name: P-STIM." (CMS HCPCS Public Meeting Agenda for supplies and "Other," May 28, 2014 attached as **Exhibit B**.) During this Public Meeting, CMS's preliminary coding decision stated: "Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for this item." *Id.*

52. As of May 28, 2014, Biegler, IHS and Eagle Advancement Institute had notice that P-STIM was not reimbursable by Medicare.

53. After CMS issued its preliminary decision rejecting Medicare reimbursement for the P-STIM System, on June 27, 2014 just as in 2006, the FDA determined the P-STIM System was the substantial equivalent to legally marketed predicate devices prior to May 28, 1976, or other reclassified devices, so Biegler was able to market the P-STIM System.

54. Although final decisions are not made at these public meetings, the applicant, Biegler, was notified of CMS's final decision that no Medicare payment was available for the P-STIM System in November. Therefore, upon information and belief, Beigler, directly or through ProMedic, Inc., confidentially received notice from CMS in November 2014 of CMS's final decision that there would be no HCPCS code added and, therefore, no Medicare payment for P-STIM.

55. On October 22, 2015, the Durable Medical Equipment Medicare Administrative Contractors ("DME MAC") issued a public Joint DME MAC Publication, titled "P-stim® Device – Correct Coding," stating:

Recently the DME MAC contractors have received inquiries about the P-stim® auricular stimulation device (Biegler GmbH). The P-stim® is a miniaturized electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture. It provides auriculo-point stimulation treatment over several days. This item is not reimbursable by Medicare. Claims submitted to the DME MACs for the P-Stim® device must be coded A9270 (Noncovered item or service).

<https://www.cgsmedicare.com/jb/pubs/news/resrc/cope695-033.html> (emphasis added) attached as **Exhibit C**.

56. After this October 2015 Joint DME MAC Publication, Biegler, IHS and Eagle Advancement Institute had actual knowledge that the P-STIM System was not reimbursable by

Medicare, and any Medicare claim submitted other than pursuant to code A9270 (Noncovered item or service) was contrary to CMS's express direction.

B. THE STIVAX SYSTEM

57. Like the P-STIM System, the Stivax System is a single use, battery-powered, electrical nerve stimulator which is used for the stimulation of the vagus nerve via the ear. The device connects an electrode cable to two sterile (radiation) acupuncture needles that have been applied by a healthcare practitioner. The stimulator connects to a clip holder on medical grade adhesive tape. The stimulator (with tape) adheres to the patient, behind the ear. *See* FDA Ltr. to Biegler, dated May 26, 2016, attached as **Exhibit D**.

58. Soon after it was publicly announced that P-STIM was unequivocally not Medicare reimbursable, Biegler, again through Promedic, Inc., sought approval from the FDA to market the Stivax System (K152571) as the substantial equivalent to its predicate device, the P-STIM System (K140788). *Id.* The products are virtually identical based on the device comparison submitted to the FDA, and states: "Biegler maintains the Stivax System is substantially equivalent to the predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with the same international standards." *Id.*

59. On May 26, 2016, the FDA granted Biegler's PMA to market the Stivax System as the substantial equivalent of the P-STIM System. *Id.*

60. Biegler engaged Solace Advancement as the U.S. distributor for the Stivax System. Solace Advancement, in turn, contracted with other distributors, such as Doc Solutions and John Doe Defendants, to sell the Stivax System across the United States.

61. In April 2017, Dr. Kuznits worked with Tena Harwick, now Accounting for Solace Advancement, to secure his Stivax System.

C. DEFENDANTS' FRAUDULENT SCHEME

62. Defendants orchestrated a fraudulent marketing scheme to sell Stivax in the United States as Medicare reimbursable, knowing at all times it was not. As a result of this fraudulent scheme, purchasers of Stivax across the nation, like Plaintiff, purchased Stivax from Defendants, administered it to patients, and billed Medicare relying on Defendants' misrepresentations that Stivax was Medicare reimbursable.

63. Stivax is manufactured by Biegler, who was also the manufacturer of P-STIM. Beginning in no later than Summer 2013, P-STIM was being marketed and distributed in the United States by Eagle Advancement Institute, which is owned by Carpenter. Carpenter is likewise the owner/operator of Solace Advancement, who became the U.S. Distributor for Stivax in 2016 after being approved by the FDA in May 2016.

64. Since 2013, Biegler and Carpenter knew or should have known P-STIM was not Medicare reimbursable. In May 2013, Biegler wrote CMS to request withdrawal of a pending request for a billing code within the HPCPS, which was granted. At this point, Biegler and Carpenter should have known P-STIM is not Medicare reimbursable.

65. In March 2014, Biegler retained the services of a consultant, Promedic, Inc. and its President Paul Dryden, to serve as its agent in submitting a new request for P-STIM to the FDA for a PMA relying on the original P-STIM as the predicate device to which it was substantially equivalent. The FDA granted this P-STIM PMA on June 27, 2014.

66. While this PMA was pending, Biegler, either directly or through Promedic, Inc., submitted a new request to CMS for approval of a HCPCS billing code for P-STIM. This

request recognized “that there are no existing HCPCS codes that adequately describe [“P-STIM”]. The minutes from the May 28, 2014, CMS concluded under “Medicare Payment” as follows: “Based on our preliminary benefit category analysis, we believe that there would be no Medicare payment for these items.”

67. In November 2014, upon information and belief, CMS sent Biegler and/or Promedic, Inc. notification of its final decision that there would be no Medicare payment for P-STIM.

68. Biegler continued to manufacture P-STIM, and Carpenter, through Eagle Advancement Institute, continued to distribute and sell P-STIM in the United States without disclosing it was not Medicare reimbursable.

69. Ultimately, on October 22, 2015, CMS publicly declared P-STIM was not Medicare reimbursable. Nonetheless, Biegler and Carpenter continued to sell P-STIM without disclosing to customers it was not Medicare reimbursable.

70. Knowing P-STIM was not Medicare reimbursable, Biegler, through its agent Promedic, Inc., sought to repackaging P-STIM as Stivax and again sell it in the United States as Medicare reimbursable. Without the Medicare eligible patient population, there is no demand for either P-STIM or Stivax.

71. In April 2016, Biegler sought FDA approval to market its repackaged P-STIM product, Stivax, and did so based on the representation that Stivax was the substantial equivalent of P-STIM. In the FDA PMA, Biegler stated: “Biegler maintains the Stivax System is substantially equivalent to the predicate device [P-STIM] in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with the same international standards.” FDA agreed and approved this request on

May 26, 2016, and concluded Stivax was the substantial equivalent to its predicate device, P-STIM.

72. Carpenter remained Biegler's U.S. distributor for Stivax pursuant to a written agreement, just as it was for P-STIM, but now under a different LLC, Solace Advancement. Biegler, Carpenter and/or Solace Advancement enlisted a distribution network throughout the United States, again pursuant to written agreements, that included Doc Solutions, Kaiser, O'Neill, ABC Corps 1-50 and John Does 1-50. This is the Stivax Enterprise and its purpose was to sell Stivax in the United States, and it did so by knowingly misrepresenting Stivax as reimbursable by Medicare.

73. The Stivax Enterprise knew Stivax was not reimbursable by Medicare, despite representing to its customers, such as Plaintiff, via mail and/or wires that Stivax was reimbursable by Medicare.

74. In furtherance of their scheme, the Stivax Enterprise employed consultants to support their knowing misrepresentation that Stivax was Medicare reimbursable.

75. The Stivax Enterprise retained Dr. Timothy Warren of Titan Medical Compliance to perpetuate their fraud. In fact, Dr. Warren had a designated email address for Stivax: stivax@titanmedicalcompliance.com. Dr. Warren and Titan Medical Compliance's role was to advise Stivax customers enlisted by the Stivax Enterprise that Stivax could be billed to Medicare, it would be reimbursed and the coding to use in doing so. This was all false.

D. PLAINTIFF IS VICTIMIZED BY DEFENDANTS' FRAUDULENT SCHEME

76. In early 2017, Kaiser, on behalf of Stivax distributor Doc Solutions, visited Neurosurgical Care at its location in Royersford, Pennsylvania to market, promote and sell

Stivax. On March 15, 2017, Kaiser introduced Dr. Kuznits to Dr. Warren via e-mail to discuss “compliance matters of the Stivax device.”

77. On March 14, 2017, Dr. Kuznits emailed Kaiser to determine whether it was appropriate to bill for Stivax under Medicare reimbursement code L8679. *See Exhibit E*, Mar. 14, 2017 Email Correspondence.

78. Kaiser responded on the same day by sending the LinkedIn page of a purported compliance officer of Doc Solutions to vouch for the Stivax Enterprise’s false claim that Stivax was Medicare reimbursable pursuant to code L8679. *Id.*

79. On March 15, 2017, Kaiser connected Dr. Kuznits with Dr. Tim Warren of Titan Medical Compliance “regarding compliance matters of the Stivax device.” *See Exhibit F*, Mar. 15, 2017 Email Correspondence.

80. On March 17, 2017, Kaiser connected Dr. Kuznits to Dr. Alex Landfield, another physician who was using Stivax. *See Exhibit G*, 3-17-2017 Email Correspondence. Kaiser connected Dr. Kuznits to Dr. Landfield, who responded on March 18, 2017, that he had been billing Medicare for Stivax based on the misrepresentations of the Stivax Enterprise, stating that “we have been billing as recommended by [Kaiser and Doc Solutions] and have not had problems.” *Id.*

81. On March 24, 2017, after Kaiser and Doc Solutions provided Medicare billing codes for Stivax, Dr. Kuznits again requested confirmation from Dr. Warren that the Stivax Enterprise’s false representation that Stivax was reimbursable by Medicare using billing code L8679. *See Exhibit H*, Mar. 24, 2017 Email.

82. On April 3, 2017, Neurosurgical Care received an email from Solace Advancement, Tena Harwick, welcoming them to Stivax.

83. On December 13, 2017, the Stivax Enterprise further memorialized its coding misrepresentations, stating: “After working closely with our compliance team over the past few weeks we are very happy to announce a new coding set that is to be used effective immediately.” *See Exhibit I*, Dec. 13, 2017 Email. Kaiser sent Dr. Kuznits a Stivax coding via email, representing that the memo was to be viewed “as a way to proceed forward” and was the product of work with their compliance team. *Id.* These coding misrepresentations were reinforced with educational conference calls on how to proceed with Stivax coding in the offices of customers of the Stivax Enterprise, including Plaintiff. *Id.*

84. This coding set again identifies Medicare billing code L6789 as an appropriate Medicare reimbursement code for Stivax restating the fraudulent scheme of the Stivax Enterprise. *Id.*

85. The Stivax Enterprise repeatedly and knowingly made these false and misleading misrepresentations with the intent of inducing their customers, including Neurosurgical Care, to purchase Stivax.

86. Neurosurgical Care relied on the misrepresentations of the Stivax Enterprise.

87. Based on these repeated fraudulent misrepresentations by the Stivax Enterprise, Neurosurgical Care began purchasing Stivax from Doc Solutions starting in April 2017 and continued to purchase Stivax up to and including through June 2018. Plaintiff would not have purchased Stivax or otherwise billed Medicare for Stivax absent these fraudulent misrepresentations.

88. Contrary to the representations of the Stivax Enterprise, L8679 was not a valid reimbursement code for use with Stivax and Stivax was not reimbursable by Medicare, just as P-STIM was not Medicare reimbursable.

89. The Stivax Enterprise intentionally and knowingly misrepresented that Stivax is reimbursable under Medicare using Medicare billing code L8679.

90. Relying on the misrepresentations of the Stivax Enterprise, Neurosurgical Care billed code L8679 for roughly 58 claims for applying the Stivax procedure, for a total of roughly \$396,973.58.

91. On July 12, 2018, SafeGuard Services LLC, the Northeastern Unified Program Integrity Contractor for the CMS conducted an audit of Neurosurgical Care and concluded the Stivax procedures reimbursed under code L8679 were not reimbursable by Medicare.

92. On September 13, 2018, Neurosurgical Care received the audit report from the on-site visit conducted by SafeGuard Services.

93. The audit report concluded that certain reimbursed procedures, including procedures that used billing code L8679 for Stivax, would be denied and are not Medicare reimbursable.

94. Immediately thereafter, Neurosurgical care stopped billing the L8679 code after becoming aware of the potential error in using this code.

95. In December 2018, Plaintiff Neurosurgical Care and Dr. Sagi Kuznits received Civil Investigative Demands from the United States Attorney's Office for the Eastern District of Pennsylvania and have been subjected to an investigation relating to their billing of Stivax under Medicare billing code L8679 as directed by the Stivax Enterprise.

96. Despite being a victim of a fraud by the Stivax Enterprise, Neurosurgical Care has been forced to spend significant funds in connection with defending itself against this investigation.

97. Neurosurgical Care is similarly situated to customers of the Stivax Enterprise across the United States. Medical practices and practitioners continue to rely on the misrepresentations of the Stivax Enterprise falsely claiming Stivax is Medicare reimbursable, so the victims of the Stivax Enterprise's fraudulent scheme are ongoing.

See e.g. <https://signalhg.com/supplies/stivax-about/>; <https://integratedspineandjoint.com/stivax/>; <https://www.paincentersa.com/stivaxneurostimulator>; <https://www.schechtermd.com/stivax/>; <https://www.spinevuetx.com/>; <https://www.anderson-medical-center.com/2019/06/14/neurostimulation-therapy-life-changing-relief-from-chronic-pain-neuropathy/>; <http://chantillyfamilypractice.com/stivax/>; <https://yourinfinitehealth.com/services/stivax-neurostimulator/>.

CLASS ALLEGATIONS

98. Plaintiff brings this action pursuant to the provisions of Rules 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of themselves and the following proposed classes:

99. Plaintiff brings these claims on behalf of the following National Injunctive / Declaratory Relief Class pursuant to Rule 23(b)(2):

All persons and entities in the United States who billed Medicare for Stivax.

100. Plaintiff brings these claims on behalf of the following National Damages Class pursuant to Rule 23(b)(3):

All persons and entities in the United States who billed Medicare for Stivax.

101. Plaintiff brings these claims on behalf of the following Pennsylvania State Damages Class pursuant to Rule 23(b)(3):

All persons and entities in the Commonwealth of Pennsylvania who billed Medicare for Stivax.

102. The proposed Classes exclude Defendants, their officers, directors and employees, as well as any judicial officer who presides over this action and members of the judicial officer's immediate family.

103. **Numerosity.** The members of the Class are so numerous and geographically dispersed that individual joinder of all Class members is impracticable pursuant to Rule 23(a)(1). Additional Class Members victimized by the Stivax Enterprise may be identified during the pendency of this action and can be notified by recognized, Court-approved notice dissemination methods, which may include U.S. Mail, electronic mail, Internet postings, and/or published notice. The identity of all Class Members is readily ascertainable from Stivax claims submitted to Medicare for reimbursement.

104. **Commonality.** There are issues of fact and law common to all class members pursuant to Rule 23(a)(2), including but not limited to:

- Whether Stivax is Medicare reimbursable;
- Whether the Stivax Enterprise knowingly misrepresented Stivax as Medicare reimbursable;
- Whether the Stivax Enterprise committed mail and / or wire fraud;
- Whether Defendants engaged in or conspired to form an enterprise for the purpose of selling Stivax pursuant to the fraudulent scheme alleged herein;
- Whether Defendants fraudulently misrepresented Stivax as Medicare reimbursable to Plaintiff and the Class;
- Whether Defendants owe a duty to Plaintiff and the Class;

- Whether Defendants violated the UTCPL in misrepresenting Stivax as Medicare reimbursable;
- Whether Defendants have been unjustly enriched by misrepresenting Stivax as Medicare reimbursable;
- The proper measure of damages and monetary relief for Plaintiff and the Classes; and
- The proper form of injunctive or declaratory relief for Plaintiff and the Classes.

105. **Typicality.** Plaintiff's claims are typical of other members of the Classes pursuant to Rule 23(a)(3) who were victimized by the fraudulent scheme set forth herein claiming Stivax is Medicare reimbursable.

106. **Adequacy.** Plaintiff will fairly and adequately protect the interests of the Classes, and have retained counsel experienced in complex class action litigation, including RICO and consumer law litigation, pursuant to Rule 23(a)(4).

107. Federal Rule of Civil Procedure 23(b)(2): The Stivax Enterprise has acted on grounds generally applicable to Plaintiff and the other members of the Class, thereby making appropriate final injunctive relief and declaratory relief with respect to the Class as a whole and end the ongoing injury caused by the fraudulent scheme alleged herein by the Stivax Enterprise.

108. The action is maintainable as a class pursuant to Rule 23(b)(3) because questions of law and fact common to the Classes predominate over any questions affecting only individual members of the Classes, and because a class action is superior to other available methods for the fair and efficient adjudication of this controversy. Defendants' conduct as described herein stems from common and uniform conduct. Class certification will also obviate the need for

unduly duplicative litigation that might result in inconsistent judgments concerning Defendants' practices. Moreover, management of this action as a class action will not present any likely difficulties. In the interests of justice and judicial efficiency, it would be desirable to concentrate the litigation of all Class Members' claims in a single action in this forum.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

VIOLATION OF 18 U.S.C. § 1962(c) – The Stivax Enterprise

109. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

110. Defendants are "persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the Stivax Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

111. The Stivax Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including its employees, agents and external consultants like Biegler, Solace Advancement, Carpenter, Dryden, Dr. Warren, Kaiser, and other as yet unknown consultants, marketing firms and distribution agents employed by Defendants to promote Stivax. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market Stivax as Medicare reimbursable. The Stivax Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Stivax Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of these entities, including Defendants, is a "person" distinct from the Stivax Enterprise.

112. Each of the Defendants, in concert with other participants in the Stivax Enterprise, created and maintained systematic links for a common purpose to aid in marketing Stivax as Medicare reimbursable while disregarding evidence to the contrary and improperly inducing

Plaintiff and Class members to purchase Stivax and submit Stivax claims to Medicare for payment based on the fraudulent misrepresentations of the Stivax Enterprise and did receive substantial revenue from the scheme to promote Stivax as Medicare reimbursable. Such revenue was exponentially greater than it would have been if Stivax was marketed appropriately to disclose that Stivax was not Medicare reimbursable. All participants of the Stivax Enterprise were aware of Defendants' control over the activities of the Stivax Enterprise in promoting Stivax. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

113. The Stivax Enterprise engaged in and affected interstate commerce, because, *inter alia*, it marketed, promoted, sold, or provided Stivax to thousands of individuals and entities throughout the United States.

114. The named Defendants exerted control over the Stivax Enterprise and management of the affairs of the Stivax Enterprise.

115. Defendants conducted and participated in the affairs of the Stivax Enterprise through patterns of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

116. Defendants' fraudulent scheme consisted of, *inter alia*: deliberately misrepresenting that Stivax was Medicare reimbursable so that Plaintiff and members of the Class paid for Stivax based on the ability to submit valid claims to Medicare for reimbursement.

117. Defendants' use of the mails and wires to perpetuate their fraud involved thousands of communications, including, but not limited to:

a. Communications with and among the enterprise participants that misrepresented the safety and risks of Stivax System amongst themselves and others;

b. Communications with patients and Class Members, including Plaintiff, inducing payments for Stivax by misrepresenting it as Medicare reimbursable;

c. Receiving the proceeds in the course of and resulting from Defendants' improper scheme;

d. Transmittal and receipt of monies from Medicare; and

e. Transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Stivax Enterprise.

118. At all times during the fraudulent scheme, Defendants had a legal and ethical obligation of candor to be honest in dealing with public and private payors, physicians and the medical community.

119. The conduct of the Stivax Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decisions and activity in connection with the Stivax Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

120. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiff and the Class. Each such racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiff and members of the Class. Defendants' racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiff and the Class.

121. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class paid hundreds of millions of dollars for Stivax that they would not have paid had Defendants not engaged in this pattern of racketeering activity.

122. The injuries to Plaintiff and members of the Class were directly and proximately caused by Defendants' racketeering activity.

123. Plaintiff and the Class, directly relied on the racketeering activities of the Defendants and the Stivax Enterprise. Plaintiff and Class members, both directly and indirectly, relied on the representations as to the Medicare reimbursability of Stivax as promoted by Defendants. Further, Defendants perpetuated this reliance by taking the steps of employing consultants to support their false claim that Stivax was reimbursable by Medicare.

124. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiff and the Class for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

125. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff and the Class have suffered damages. Plaintiff and the Class members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

SECOND CAUSE OF ACTION

VIOLATION OF 18 U.S.C. § 1962(d) – RICO

Conspiracy

126. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

127. Section 1962(d) of RICO provides that it “shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section.”

128. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Stivax Enterprise described previously through a pattern of racketeering activity. The corporate defendants conspired with, *inter alia*, consultants, sales representatives, medical professionals, academics and other intermediaries to promote Stivax and suppress information about the Stivax Enterprise’s false representation that Stivax was Medicare reimbursable.

129. Defendants’ co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class out of money.

130. The nature of the above-described Defendants’ co-conspirators’ acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

131. As a direct and proximate result of Defendants’ overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the Class have been and are continuing to be injured in their business or property as set forth more fully above.

132. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;
- b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;
- c. Multiple instances of wire fraud violations of 18 U.S.C §§ 1341 and 1346;
- d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

133. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have purchased Stivax for use on Medicare eligible patients and submitted invalid claims for payment to Medicare for Stivax pursuant to billing code L8679 that they would not have made had Defendants not conspired to violate 18 U.S.C. § 1962(c).

134. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by Defendants' racketeering activity as described above.

135. Plaintiff and the Class directly relied on the racketeering activities of the Defendants and the Stivax Enterprise. Plaintiff and the Class members, both directly and indirectly, relied on the representations that Stivax was Medicare reimbursable as promoted by Defendants. Further, Defendants perpetuated this reliance by taking the steps of employing consultants to support their false claim that Stivax was reimbursable by Medicare.

136. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant is liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

137. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff and the Class have suffered damages. Plaintiff and the Class members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

THIRD CAUSE OF ACTION

**VIOLATIONS OF THE PENNSYLVANIA
UNFAIR TRADE PRACTICES AND CONSUMER
PROTECTION LAW (“UTPCPL”), 73 PA.C.S.A.
§ 201-1 ET SEQ.**

138. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

139. At all times material hereto, Defendants were a manufacturer, marketer, seller and/or distributor of Stivax within the meaning of the Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPCPL”), 73 Pa.C.S.A. § 201-1 *et seq.*

140. At the times material hereto, the conduct described above and throughout this Complaint took place within the Commonwealth of Pennsylvania and constitutes unfair methods of competition or unfair or deceptive acts or practices in violation of § 201-2(4), (v), (vii) and (xxi) of UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

141. The UTPCPL applies to the claims of all the class members because the conduct which constitutes violations of the UTPCPL by Defendants occurred within the Commonwealth of Pennsylvania.

142. At all times relevant and material hereto, Defendants conducted trade and commerce within the meaning of the UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

143. Defendants' deceptive marketing scheme concerning Stivax violates the UTPCPL because, *inter alia*, Defendants:

- a. Knowingly conceal, suppress, misrepresent or omit material information regarding Stivax's eligibility for Medicare reimbursement with the intent to induce reliance upon such concealment, suppression, misrepresentation or omission;
- b. Knowingly misrepresent that Stivax is eligible for reimbursement by Medicare pursuant to any billing code, including L8679; and
- c. Market, promote, and advertise Stivax as eligible for Medicare reimbursement is deceptive and unfounded.

144. Defendants' concealment, suppression, omissions, misrepresentations, deceptions, and unconscionable and fraudulent practices has the tendency, capacity, and likelihood to deceive Plaintiff and the Class members.

145. Defendants intend, or consciously disregard, that Plaintiff and the Class members rely on its concealment, suppression, omissions, misrepresentations, deceptions, and unconscionable and fraudulent practices, so that they are able to sell Stivax to Plaintiff and the Class.

146. Defendants' concealment, suppression, omissions, misrepresentations, deceptions, and unconscionable and fraudulent practices cause Plaintiff and the Class members to suffer ascertainable losses in the amount of the monies paid for Stivax, or paid in connection with any governmental action relating to Medicare reimbursement for the Stivax.

147. Defendants deceived and continue to deceive consumers. This conduct constitutes unfair or deceptive acts or practices within the meaning of the UTPCPL. This effects or this illegal conduct is ongoing with no indication that it will cease.

148. Defendants' actions in connection with the advertising, marketing, selling and distribution of Stivax as set forth herein evidences a lack of good faith, honesty and observance of fair dealings so as to constitute unconscionable commercial practices, in violation of UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

149. Plaintiff and the Pennsylvania Class members would not have purchased Stivax had they known of Defendants' deceptive and misleading marketing scheme, or the extent of said scheme.

150. Plaintiff and the Class members are accordingly harmed by Defendants' conduct in violation of the UTPCPL, 73 Pa.C.S.A. § 201-1 *et seq.*

151. By reason of Defendants' violations of the UTPCPL described above, Plaintiff and the Pennsylvania Class members are entitled to recover treble damages, including but not limited to a full refund of all monies reimbursed by Medicare to Plaintiff and Class members have received for Stivax claims, any monies paid by Plaintiff and Pennsylvania Class members in connection with defending governmental claims relating to improper Stivax Medicare reimbursements, along with equitable relief prayed for herein in this Complaint.

FOURTH CAUSE OF ACTION

UNJUST ENRICHMENT

152. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

153. Defendants have been and continue to be enriched by their fraudulent acts and omissions alleged herein for all states wherein class members reside.

154. In exchange for payments they made for Stivax and at the time these payments were made, Plaintiff and Class members expected that Stivax was reimbursable by Medicare as

expressly represented by Defendants.

155. Defendants voluntarily accepted and retained these payments with full knowledge and awareness that, as a result of their wrongdoing, Plaintiff and Class members paid for Stivax with the intention of submitting claims to Medicare for reimbursement.

156. These fraudulent acts and omissions allow Defendants to unlawfully gain profits that would not have been gained but for Defendants' fraudulent acts and omissions.

157. Plaintiff and the Class members suffered damages due to Defendants' acts and omissions as alleged herein.

158. Defendants have and continue to be unjustly enriched as a result of their fraudulent acts and omissions.

159. Defendants lack any legal justification for engaging in a course of fraudulent acts and omissions as alleged herein at Plaintiff's and the Class' expense.

160. No other remedy at law can adequately compensate Plaintiff and Class members for the damages occasioned by Defendants' conscious choice to engage in a course of fraudulent acts and omissions.

161. Plaintiff and Class members are entitled in equity to seek restitution of Defendants' wrongful profits, revenues and benefits to the extent and in the amount, deemed appropriate by the Court and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

FIFTH CAUSE OF ACTION

FRAUDULENT MISREPRESENTATION

162. Plaintiff repeats, realleges, and incorporates here by reference each of the foregoing and subsequent allegations of this Complaint as if set forth fully herein.

163. Defendants represented to Plaintiff on multiple occasions that billing code L8679 for Stivax procedures was appropriate for reimbursement from Medicare.

164. These representations were material to the transactions at issue because Plaintiff purchased Stivax and billed Medicare as instructed by Defendants.

165. Defendants made these misrepresentations falsely, with knowledge of their falsity, or with recklessness as to whether the misrepresentations were true or false.

166. Defendants made these misrepresentations with the intent of misleading Plaintiff and the intent of inducing Plaintiff to rely on the misrepresentations to induce Plaintiff to begin purchasing Stivax and submitted claims to Medicare for reimbursement of Stivax, which are ongoing for members of the Classes.

167. Plaintiff and the Classes justifiably relied on these misrepresentations and, in reliance on the misrepresentations, purchased Stivax and billed Stivax to Medicare according to the codes offered by Defendants.

168. As a direct and proximate cause of Defendants' fraudulent misrepresentations, Plaintiff and the Classes were harmed in an amount to be determined at trial.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

169. Plaintiff repeats, realleges, and incorporates here by reference each of the foregoing and subsequent allegations of this Complaint as if set forth fully herein.

170. Defendants negligently misrepresented to Plaintiff and the Classes that billing code L8679 for Stivax procedures was appropriate for reimbursement by Medicare.

171. Defendants knew or should have known that the material misrepresentations they made were false.

172. Defendants knowingly made these material misrepresentations with the intent to induce Plaintiff and members of the Classes to begin purchasing and continue to purchase and use Stivax.

173. As a direct and proximate cause of Defendants' negligent misrepresentations, Plaintiff and the Classes were harmed in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION

NEGLIGENCE

174. Plaintiff repeats, realleges, and incorporates here by reference each of the foregoing and subsequent allegations of this Complaint as if set forth fully herein.

175. Defendants provided information to Plaintiff and members of the Classes which they knew or should have known was incorrect and false.

176. Plaintiff and the Class members reasonably relied on Defendants' representations and instructions concerning billing codes for Stivax for Medicare reimbursement.

177. Defendants owed Plaintiff and the Classes a duty to provide accurate information with respect to billing codes for Stivax that Defendants promoted, marketed, and sold to Plaintiff and the Classes based on the false premise that it was reimbursable by Medicare.

178. Defendants breached this duty by providing materially false information regarding billing codes for the product that Defendants promoted, marketed, and sold to Plaintiff and the Classes.

179. As a direct and proximate cause of this breach, the Plaintiff and the Classes suffered damages in an amount to be determined at trial.

DEMAND FOR JURY TRIAL

180. Plaintiff demands a jury trial for itself and all members of the certified class for damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor and against Defendants and provide the following relief:

- A. An award for Neurosurgical Care and the members of the Classes for all damages incurred in purchasing and billing for Stivax under codes that Defendants fraudulently provided and invalid claims submitted to Medicare for payment;
- B. An award for Neurosurgical Care and the members of the Classes for the sums for which any governmental entity imposed for invalid submissions to Medicare for Stivax claims pursuant to billing code L8679;
- C. An award of reasonable attorneys' fees and costs;
- D. An award to Plaintiff of such other and further relief as this Court may deem just and proper.

Dated: February 6, 2020



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